

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

07/02/2002

Finnegan Henderson Farabow Garrett & Dunner 1300 I Street NW Washington, DC 20005

EXAMINER			
O SULLIVA	N, PETER G		
ART UNIT	CLASS-SUBCLASS		

536-017400

1621
DATE MAILED: 07/02/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,909	03/09/2001	Philip James Parsons	07203.0023	3335

TITLE OF INVENTION: MORPHINE-6-GLUCURONIDE SYNTHESIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1280	\$0	\$1280	10/02/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>, THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT, SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
- A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.
- □ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- II. PART B FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE

Commissioner for Patents Washington, D.C. 20231 (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block I Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 07/02/2002 Finnegan Henderson Farabow Garrett & Dunner Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below. 1300 I Street NW Washington, DC 20005 (Depositor's name) (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/700.909 03/09/2001 Philip James Parsons 07203.0023 3335 TITLE OF INVENTION: MORPHINE-6-GLUCURONIDE SYNTHESIS APPLN. TYPE SMALL ENTITY **ISSUE FEE PUBLICATION FEE** TOTAL FEE(S) DUE DATE DUE nonprovisional \$1280 \$1280 10/02/2002 **EXAMINER** ART UNIT **CLASS-SUBCLASS** O SULLIVAN, PETER G 1621 536-017400 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. single firm (having as a member a registered attorney or agent) and the names of up to 2 ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer registered patent attorneys or agents. If no name is listed, no name will be printed. Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government 4a. The following fee(s) are enclosed: 4b. Payment of Fee(s): ☐ A check in the amount of the fee(s) is enclosed. ☐ Issue Fee □ Payment by credit card. Form PTO-2038 is attached. ☐ Publication Fee ☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____(enclose an extra copy of this form). ☐ Advance Order - # of Copies Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. (Authorized Signature) (Date) NOTE; The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

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Commissioner for Patents, Washington, DC 20231.



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,909	03/09/2001	Philip James Parsons	07203.0023	3335
75	590 07/02/2002		EXAMIN	ER
Finnegan Henderson Farabow			O SULLIVAN, PETER G	
Garrett & Dunner 1300 I Street NW			ART UNIT	PAPER NUMBER
Washington, DC 20005			1621	
			DATE MAILED: 07/02/2002	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.usplc.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,909	03/09/2001	Philip James Parsons	07203.0023	3335
75	590 07/02/2002		EXAMIN	ER
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Garrett & Dunner		_		
1300 I Street NW			ART UNIT	PAPER NUMBER
Washington, DC 20005 UNITED STATES			1621	
		D	ATE MAILED: 07/02/2002	

Notice of Fee Increase on October 1, 2002

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2002, then the amount due may be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on October 1, 2002. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Notice of Proposed Rulemaking, 67 Fed. Reg. 30634, 30636 (May 7, 2002). Although a change to the amount of the publication fee is not currently proposed for October 2002, if the issue fee or publication fee is to be paid on or after October 1, 2002, applicant should check the USPTO web site for the current fees before submitting the payment. The USPTO Internet address for the fee schedule is: http://www.uspto.gov/main/howtofees.htm,

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after October 1, 2002 (or mailed with a certificate of mailing on or after October 1, 2002), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Effective October 1, 2002, 37 CFR 1.18 is proposed to be revised to change the patent issue fees as set forth below. As stated above, the final fees may be a different amount, and applicant should check the web site given above when paying the fee.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:

By a small entity (Sec. 1.27(a))--\$655.00 By other than a small entity--\$1,310.00

(b) Issue fee for issuing a design patent:

By a small entity (Sec. 1.27(a))--\$235.00 By other than a small entity--\$470.00

(c) Issue fee for issuing a plant patent:

By a small entity (Sec. 1.27(a))--\$315.00 By other than a small entity--\$630.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

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Notice of Allowability

Application No. 09/700,909

Applicant(s)

Parsons et al.

Examiner

Peter O'Sullivan

Art Unit 1621



The MAILING DATE OF this communication appears on the co	over sneet with the correspondence address
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAIN (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriat THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. The initiative of the Office or upon petition by the applicant. See 37 CFR 1.	te communication will be mailed in due course. This application is subject to withdrawal from issue at
1. This communication is responsive to	17306
2. X The allowed claim(s) is/are 1-7	€\/\.'
3. The drawings filed on are accepted by th	
4. X Acknowledgement is made of a claim for foreign priority under	
a) ☒ All b) ☐ Some* c) ☐ None of the:	
1. Certified copies of the priority documents have been received.	ived.
2. Certified copies of the priority documents have been received.	
Copies of the certified copies of the priority documents hat application from the International Bureau (PCT Rule 17) *Certified copies not received:	ave been received in this national stage .2(a)).
5. Acknowledgement is made of a claim for domestic priority unde	
(a) \square The translation of the foreign language provisional application	n has been received.
6. Acknowledgement is made of a claim for domestic priority unde	er 35 U.S.C. §§ 120 and/or 121.
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this community of the comply will result in ABANDONMENT of this EXTENDABLE.	
7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s)	he attached EXAMINER'S AMENDMENT or NOTICE OF why the oath or declaration is deficient.
8. CORRECTED DRAWINGS must be submitted.	
(a) \square including changes required by the Notice of Draftsperson's P	Patent Drawing Review (PTO-948) attached
1) \square hereto or 2) \square to Paper No	
(b) including changes required by the proposed drawing correcti approved by the examiner.	on filed, which has been
(c) \square including changes required by the attached Examiner's Amer Paper No	ndment/Comment or in the Office action of
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should each sheet. The drawings should be filed as a separate paper with a transmitt	
9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOG attached Examiner's comment regarding REQUIREMENT FOR TH	
Attachment(s)	
1 Notice of References Cited (PTO-892)	2 Notice of Informal Patent Application (PTO-152)
3 Notice of Draftsperson's Patent Drawing Review (PTO-948)	4 Interview Summary (PTO-413), Paper No
5 Information Disclosure Statement(s) (PTO-1449), Paper No(s).	6 X Examiner's Amendment/Comment
 7	8 X Examiner's Statement of Reasons for Allowance
	PRIMARY EXAMINER

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Art Unit: 1621

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to a process for preparing M6G.

Group II, claim(s) 8-10 and 13, drawn to glucouronate derivatives and methods.

Group III, claim 12, drawn to methods of using a pyridine derivative

Group IV, claim(s) 11, drawn to a method of using morphine derivatives.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-IV involve compounds that are structurally diverse lacking the common feature of a glycosidic link. The compounds of group II could be used to prepare antibiotics, the compounds of group III could be used as acid acceptors in amination reactions and the compounds of group IV to treat diarrhoea...

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Art Unit: 1621

3. During a telephone conversation with Mr. Garret on 18 May 2002 a provisional election was made without traverse to prosecute the invention of group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Garret on 18 May 2002.

- 6. The application has been amended as follows:
 - 1. Claims 8-13 were cancelled.
 - 2. In claim 3, line 1, "1 or" was deleted.

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Art Unit: 1621

3. In claim 4, line 1, "any preceding claim" was deleted and -- claim 1 -- was inserted in lieu thereof.

- 4. In claim 5, line 1, "any preceding claim" was deleted and -- claim 1 -- was inserted in lieu thereof.
- 5. In claim 6, line 1, "any preceding claim" was deleted and -- claim 1 -- was inserted in lieu thereof.
- 7. The following is an examiner's statement of reasons for allowance: The instant invention is held to be in condition for allowance inasmuch as the prior art does not teach or suggest applicants' invention. WO 93/03051, cited as state of the art only, reacts a trichloroacetimidoylglucuronate with an acetylmorphine. Multiple changes would have to be made to the reaction of WO 93/03051 to make applicants' process.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter O'Sullivan whose telephone number is (703) 308-4526.

PETER O'SULLIVAN
PRIMARY EXAMINER
GROUP 1200